



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Zhenwei Miao, et al.
Application No: 10/774,047 Group No: 1624
Filed: February 06, 2004 Examiner: Noble E. Jarrell
Confirmation No.: 4991
Title: MACROCYCLIC HEPATITIS C SERINE PROTEASE INHIBITORS

REQUEST FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT
UNDER 37 CFR 1.705

Dear Sir:

This letter is to request reconsideration of the decision mailed September 10, 2009 and correct the Patent Term Adjustment under Rule 705. The \$200 fee required by Rule 18(e) has been paid previously. No terminal disclaimer has been filed in this application.

The Issue Notification now states that the Patent Term Adjustment is 953 days. Patentee does not agree with this determination.

Patent term extensions are available under 35 U.S.C. § 154(b)(1)(A)-(B). 35 U.S.C. § 154(b)(1)(A) provides for extension of patent terms for certain specified kinds of Patent and Trademark Office (PTO) delay while 35 U.S.C. § 154(b)(1)(B) provides for extension whenever the patent prosecution takes more than three years. A period of delay under § 154(b)(1)(A) is referred to as A-delay and a delay under § 154(b)(1)(B) is referred to as B-delay. 37 CFR 1.703(a) and 1.703(b) corresponds to A-delay and B-delay, respectively. Applicants do not dispute the Office's calculations of 740 days of delay for the period of time to issue a first action and the deduction of 27 days on behalf of the Applicant.

However, Applicants disagree with the additional determinations that the Office has not delayed under Rule 703.

The Office mailed a restriction requirement on April 16, 2007. Applicants filed a reply to the restriction requirement on June 14, 2007. The four month period under

703(a)(2) expired on October 14, 2007. An action was mailed on July 24, 2007. However, during the interview on October 15, 2007, the Examiner agreed that the Office Action contained an incorrect requirement and would need to be reissued. A second Office Action was mailed on January 8, 2008, with yet another supplemental action on January 22, 2008. Thus, a complete action in reply to the Applicant letter of June 14, 2007 was not mailed until January 22, 2008. Thus, a term of 100 days representing the days between October 14, 2007 and January 22, 2008 should be added to the Patent Term Adjustment.

The Decision on Petition disagrees, stating that the mailing of an action, albeit an incomplete action, is sufficient to “stop” the clock for the PTO. The statutory intent of 35 USC 154(b) is to ensure that the PTO act diligently in bringing prosecution to a close and, when it fails to do so, to reimburse Applicants for the patent term lost by the delay. Mailing incomplete actions to “stop” the clock and which are not completed for several months is completely contradictory to the statutory intent. Note that incomplete amendments do not stop the Applicants’ clock and filing supplemental papers by an Applicant are deemed to invoke “Applicant delay.” Incomplete office actions should be similarly treated.

The Decision reasons that the July and first January office actions were not “vacated.” However, these two office actions were certainly deemed to be deficient, were replaced by another action and the Office clearly had no intent to require a reply to the earlier office actions. The word “vacate” is understood to mean “make void”. In essence, these actions were “voided” and, as such, “vacated.” The fact that the word was not used does not change the fundamental effect of mailing office actions intended to replace an earlier one.

Further, the issue fee was paid on December 22, 2008. The patent will issue on October 13, 2009. Thus, an additional delay of 174 days under Rule 703(a)(6) is due.

In addition to the change to the Patent Term Adjustment requested above under 703(a), Applicants request the addition of days delayed under Rule 703(b). The delay under Rule 703(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35

U.S.C. 111(a) with the exception that days of delay under Rule 703(a) may not overlap with the days of delay under Rule 703(b).¹ In the instant case, the days delayed under Rule 703(b) began on February 6, 2007, three years from the filing date of February 6, 2004, and will end on the issue date of October 13, 2009 for a total of 980 days. The days that overlap with the days under Rule 703(a) discussed above are the periods between (1) February 6, 2007 and April 16, 2007, (2) October 14, 2007 and January 22, 2008 (if the Patent Office reverses its decision of September 10, 2009), and (3) April 22, 2009 to October 13, 2009. A total of 343 days of overlap for all three periods or 243 days for periods (1) and (3) are believed to be in order, depending on the decision with respect to period (2).

In the event that the Office reverses its decision dated September 10, 2009 with respect to the Office Delay under Rule 703(a)(2), it is believed that the patent term adjustment should be calculated as follows:

$$740 \text{ days} + 100 \text{ days} + 174 \text{ days} + 980 \text{ days} - 343 \text{ days overlap} - 27 \text{ days} = 1651 \text{ days}$$

In the event that Office maintains its decision dated September 10, 2009 with respect to the Office Delay under Rule 703(a)(2), it is believed that the patent term adjustment should be calculated as follows:

$$740 \text{ days} + 174 \text{ days} + 980 \text{ days} - 243 \text{ days overlap} - 27 \text{ days} = 1651 \text{ days}$$

¹ It appears that the Office views the period of overlap differently as it awarded only 66 days. It is not clear how the 66 days is derived. It appears that the Office took the 980 days of delay under Rule 703(b) and simply subtracted the entire period under Rule 703(a). However, a recent decision, *Wyeth v. Dudas*, the District Court of the District of Columbia held that any days considered to be delayed under Rule 703(a) delay and that occur prior to the third year anniversary that commences a calculation of the days delayed under the Rule 703(b) delay period cannot be said to be "overlapping." (1:07-cv-01492-JR, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008)).

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Accordingly, a patent term adjustment of 1,651 days is requested.

Respectfully submitted,

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